ever, many governments are forsaking such tactics to focus on shorter-term quick fixes. Whilst recognising that risks-sharing agreements represent an important market access strategy, the objective of this research was to examine if the marked expansion in number of risk-sharing agreements through 2007-2010 is still continuing, or if there is a gradual levelling off across the world. **METHODS:** Secondary research was conducted examining reimbursement decisions around the world, with a special focus on Australia, Belgium, Brazil, Canada, China, France, Germany, Hungary, Italy, The Netherlands, New Zealand, Poland, Russia, Spain, Turkey, UK and United States. This was supplemented by primary research with payors and organisations through interviews in native languages to identify potential risk-sharing agreements outside the public domain as well as general opinions. **RESULTS:** Thirty-two new risk-sharing agreements were found in the period of review (May 2011 - May 2012), which is roughly in-line with the rate found in previous years. The number of new drugs with risk-sharing agreements attached to them actually declined, and most new agreements are being negotiated for drugs which already have one in place. The majority of agreements tend to be finance-based, although new performance-based agreements continue to emerge, including in emerging markets. The majority continue to focus on the oncology arena. **CONCLUSIONS:** Although risk-sharing continues to be a routine part of market access in many countries, there appears to be a notable "levelling off" of the rapid expansion of this strategy in previous years. This is relatively unsurprising as it reaches a natural plateau, but still notable against the background of ongoing global austerity.

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IMPACT OF A FINANCIAL RISK-SHARING SCHEME ON BUDGET-IMPACT ESTIMATIONS: A GAME-THEORETIC APPROACH

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OBJECTIVES: As part of the process of updating the National List of Health Services (NLHS) in Israel, both health-plans ('payers') and manufacturers provide estimates on the expected number of patients that will utilize the drug. Currently, payers face major financial consequences when actual drug utilization is significantly higher than the allocated budget. We suggest a risk-sharing model that imposes a potential penalty on the two stakeholders; if the actual number of patients exceeds the manufacturer's prediction, the manufacturer will reimburse the payers by a rebate rate of α from the deficit. In case of under-utilization, payers will refund the government at a rate of γ from the surplus budget. Our study objective was to identify the optimal early estimations of both 'players' prior to and after implementation of the risk-sharing scheme. **METHODS:** Using a Game-Theoretic approach, in which both players' statements are considered simultaneously, we examined the impact of risk-sharing within a given range of rebate proportions (α, γ), on players' early budget estimations. **RESULTS:** With no risk-sharing, manufacturers and health-plans will choose to announce the smallest and highest number of patients, from the cumulative distribution function of patients, respectively. When increasing "α" to be over 50%, manufacturers will announce a larger number and health-plans will announce a lower number of patients than they would without risk-sharing, thus, substantially decreasing the gap between their estimates. On the other hand, increasing γ changes players' estimates only slightly. **CONCLUSIONS:** In reaction to applying a substantial risk-sharing rebate "α" on the manufacturer, both players are expected to adjust their budget estimates towards an optimal equilibrium. Since manufacturers do not benefit directly from the health-plans' rebate to the government, increasing α is a better vehicle for reaching the desired equilibrium rather than increasing γ, as both players are substantially influenced by the manufacturer's rebate α.

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RECENT GLOBAL INSIGHTS INTO RISK SHARING AGREEMENTS: A COMPARATIVE ANALYSIS

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OBJECTIVES: To evaluate whether risk sharing agreements (RSA) are utlilised by health technology assessment (HTA) agencies over the world. Similarities and differences between appraisals where an RSA is applied will be assessed across the different agencies. **METHODS:** Nine select HTA agencies across the globe (MOHTLC, NICE, PBAC, SMC, TLV, INESSS, CADTH, NCPE, and AWMSG) were scanned to determine what type of RSAs were adopted for drug appraisals. Only single technology appraisals published between 2010 and April 2012 were included in the search. Comparisons were made between the agencies to determine whether any common trends were present, particularly for appraisals on the same drug. **RESULTS:** In total 100 HTAs (74 treatments) were identified that included an RSA across the 9 agencies. The number of RSAs identified per agency was as follows: MOHTLC (24 HTAs), NICE (23), PBAC (15), SMC (14), TLV (10), INESSS (7), CADTH (6), NCPE (4), and AWMSG (2). Overall there was very little consistency between agencies as to which treatments included an RSA. For the very few treatments with an RSA fwith more than one agency, the type of agreement applied between these agencies varied. RSAs identified in NICE submissions were often elaborate whilst the remaining agencies usually applied simple discounts, price reductions or cost agreements. Interestingly, all recently submitted oncology therapies to INESSS were required to have a shared financial risk agreement for recommendation. **CONCLUSIONS:** RSAs are applied by several HTA agencies from around the world. There does not seem to be consistency in RSAs amongst the different agencies. If an RSA is made for a particular treatment for one agency, this does not mean an RSA will be applied by another agency for the same treatment.

HEALTH CARE USE & POLICY STUDIES - Conceptual Papers

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PAEDIATRIC USE MARKETING AUTHORISATION (PUMA): THE CHALLENGES OF COST-EFFECTIVENESS MODELLING WHERE LIMITED CLINICAL TRIAL INFORMATION IS AVAILABLE

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Paediatric use marketing authorisation (PUMA) was developed by the European Medicines Agency to promote the development of paediatric formulations of products that are already authorised but are no longer covered by intellectual property rights (patent, supplementary protection certificate). There are a number of aims of which 2 are of interest here: ensure that medicines used to treat children are subject to high-quality, ethical research and are appropriately authorised; and achieve these objectives without subjecting the paediatric population to unnecessary clinical trials and without delaying the authorisation for other patients. In September 2011 BUCCOLAM® was the first product to receive a PUMA for the treatment of prolonged, acute, convulsive seizures. Products approved in this way are likely to have less comparative data which makes both Pharmacoeconomic value demonstration and assessment more challenging. In order to undertake cost-effectiveness analyses for BUCCOLAM to inform HTAs, de novoprimary data gathering was required. This included: gathering expert views on treatment pathways, downstream consequences of seizures and utilities (utilising a Delphi process); gathering information on treatment pathways and the frequency and locale of seizures (patient/carer surveys); and a cost-gathering exercise with hospitals. The SMC and AWMSG were willing to accept the data gathered above in combination with extensive sensitivity analysis which addressed the economic uncertainties resulting from the limited clinical trial data. In other countries, where reimbursement is linked to the strength of efficacy evidence it can be very difficult for a PUMA product to demonstrate value. The PUMA process is relatively new and it may be necessary for HTA bodies to review their requirements for interventions licensed via this regulatory process and prepare an alternative pathway to assess their value. In many cases this approach has been taken for orphan and ultra-orphan diseases where the same data challenges may apply.

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WHY DO PATIENTS ENGAGE IN MEDICAL TOURISM?

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Medical tourism is commonly perceived and popularly depicted as an economic issue, both at the system and individual levels. The decision to engage in medical tourism, however, is more complex, driven by patients' unmet need(s), the nature of services sought and the manner by which treatment is accessed. In order to harness and promote the opportunities medical tourism offers, as well as address and contain attendant threats, an informed decision is crucial. This paper aims to enhance the current knowledge on medical tourism by isolating the types of decisions that patients make – and based on the existing literature, proposing a theoretical sequence in opting for or against medical care abroad. It proposes a sequential decision-making process to engage in medical tourism, which includes considerations of the required treatments, location of treatment, and the quality and safety issues that are attendant to seeking care. Where patient involvement is regarded as crucial in achieving the desired health outcomes and promoting the efficient use of resources, the active role of the patient under medical tourism should prove to be valuable. In consideration of the challenges and opportunities that medical tourism offers, bringing forward scholarship on the globalization of health care in general and of medical tourism in particular, calls for developing empirical evidence on this increasingly popular and complex form of accessing and provision of medical care.

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ADOPTION OF NEW TECHNOLOGIES IN TWENTY ESTABLISHED AND EMERGING MARKETS

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OBJECTIVES: The purpose of this analysis was to evaluate drivers affecting market access for new technologies in twenty established and emerging markets (Australia, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Italy, India, Japan, Norway, Poland, Russia, Spain, Turkey, the UK, Sweden, and Switzerland). **METHODS:** Health care spend, government debt ratio, financing structure and regulatory policy were examined relative to their impact on market access. Comprehensive reviews of publicly available literature, data sources, policies and regulations were performed for each country of interest. **RESULTS:** Entrants to markets without an official regulatory body face stiff competition from non-standard or counterfeit comparator products. At the other extreme, some countries require substantial country-specific clinical evidence for approval, making them cost-prohibitive for smaller manufacturers . High government debt ratios were found to be predictive of increased austerity measures, which broadly have a negative impact on market access for new technologies, placing pressure on downward pricing in countries that use national fee schedules. DRG-based systems were found to be more receptive than markets that reimbursed inpatient facilities through annual global payments. The likelihood of a medical device receiving an HTA in any country is dependent on (1) regulatory requirements for market entry and (2) the existence of device-focused HTAs, which are not as pervasive as HTAs for pharmaceuticals. In countries where inpatient procedures are funded by global payments, hospital level reviews are more likely than a national assessment for medical device technologies. In countries where fee-for-service dominates device